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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,992	02/04/2002	David S. Hungerford	02-030-PA-DIV	6179

7590 05/18/2007
ARMSTRONG, WESTERMAN & HATTORI, LLP
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EXAMINER

SCHILLINGER, ANN M

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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05/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/066,992	Applicant(s) HUNGERFORD ET AL.	
	Examiner Ann Schillinger	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/29/2002</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Terminal Disclaimer

The terminal disclaimer filed on 3/16/2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 8/14/2001 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7, 9, and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Cubicciotti (US Pat. No. 6,287,765). Cubicciotti discloses the following of claim 7: a crosslinked polymer prepared by crosslinking a polysaccharide with a polyamine (col. 63, lines 43-65; col. 175, lines 30-64) said polymer to be used for cell culture and preparing scaffolds or templates for tissue replacement (col. 7, lines 45-60; col. 16, lines 10-17; col. 206, lines 26-39).

Cubicciotti discloses the following of claim 9: the crosslinked polymer of claim 7 wherein the polysaccharide is selected from the group consisting of dextran, cellulose, arabinogalactan, pullulan and amylase (col. 179, lines 46-61).

Cubicciotti discloses the following of claim 10: in a method of cell culture wherein cells are cultured on microcarrier beadlets the improvement comprising growing the cells on a

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polyamine cross-linked polysaccharide polymer (col. 63, lines 43-65; col. 175, lines 30-64) of claim 7 and thereafter separating the cells from the microcarrier beadlets (col. 238, lines 1-13) by digestion with an enzyme compatible with the polysaccharide (col. 121, line 64 through col. 122, line 14).

Claims 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldenberg (US Pat. No. 5332567). Goldenberg discloses a crosslinked polysaccharide derivative comprising dextran and ethylenediamine coupled with amines and imines potentially in a beaded shape (Col. 9, lines 44-57; col. 11, lines 43-51; col. 12, lines 5-40; col. 22, line 65 through col. 23, line 16). Please Note: the method of production for the derivative is the same as the present invention and therefore the products would be the same. Also, the recitations of a beadlet or a scaffold in claim 17, have not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand-alone.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cubicciotti in view of Oliver et al. (US Pat. No. 5897987). Cubicciotti discloses the invention substantially as claimed, including the crosslinking agent of claim 8 (see col. 246, lines 29-44). However, Cubicciotti does not disclose the use of arabinogalactan. Oliver et al. teaches the use of arabinogalactan in col. 3, lines 5-22; col. 3, line 35 through col. 4, line 11) for the purpose of protecting the viability of the cells in the medium. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use arabinogalactan in order to protect the viability of the cells in the medium.

Claims 11-14, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cubicciotti or Goldenberg in view of Leong et al. (US Pat. No. 5686091). Cubicciotti and Goldenberg disclose the invention substantially as claimed, however, they do not disclose the use of chondrocytes. Oliver et al. teaches the use of chondrocytes in col. 1, lines 46 through col. 2, line 8) for the purpose of increasing the cell density. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use chondrocytes in order to increase the cell density.

Cubicciotti discloses the following of claim 14: the method of claim 13 wherein after the cells are plated on the scaffold or template for growth thereon, the scaffold or template is surgically implanted into the cartilage tissue (col. 131, lines 51-61).

Response to Arguments

Due to Applicant's amendments the 35 USC 112 rejection has been withdrawn.

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Upon new search and considerations, the above references have been found that read on the claims.

Applicant's arguments filed 3/16/2005 have been fully considered but they are not persuasive. Applicant contends that the Goldenberg reference does not disclose a beadlet structure, but this reference does disclose this in col. 22, lines 65 through col. 23, line 16. Regarding the indications of a cell culture or scaffold, it has been held that a recitation such as this, with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger
May 8, 2007

A. Stewart
ALVIN J. STEWART
PRIMARY EXAMINER